

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date

April 13, 2004

From

Susan Thompson, HFS-810, Division of Dietary Supplement Programs Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN

Subject

Closing of Petitions for Stay of Action

To

Docket Numbers 93N-0478/PSA1, 90N-135D/PSA1, 91N-384D/PSA1, 85N-061D/PSA1, 93N-0481/PSA2, 93N-480A/PSA2, 93N-480C/PSA2, 93N-480F/PSA2, 93N-480O/PSA2 and 93N-480Z/PSA2

On January 31, 1994, Ronald C. Nesmith, of Dilling and Dilling in Chicago, Illinois, submitted on behalf of the National Council for Improved Health, 10 citizen petitions requesting that the Food and Drug Administration (FDA) act to stay implementation of the effective dates of the actions pertaining to the following:

- (1). DIETARY SUPPLEMENT; ESTABLISHMENT OF DATE OF APPLICATION (Docket No. 93N-0478/PSA1)
- (2). FOOD LABELING; GENERAL REQUIREMENTS FOR NUTRITION LABELING FOR DIETARY SUPPLEMENTS OF VITAMINS, MINERALS, HERBS, OR OTHER SIMILAR NUTRITIONAL SUBSTANCES (Docket No. 90N-135D/PSA1)
- (3). FOOD LABELING; REQUIREMENTS FOR NUTRIENT CONTENT CLAIMS FOR DIETARY SUPPLEMENTS OF VITAMINS, MINERALS, HERBS, AND OTHER SIMILAR NUTRITIONAL SUBSTANCES (Docket No. 91N-384D/PSA1)
- (4). FOOD LABELING; REQUIREMENTS FOR HEALTH CLAIMS FOR DIETARY SUPPLEMENTS (Docket No. 85N-061D/PSA1)
- (5). FOOD LABELING: HEALTH CLAIMS AND LABEL STATEMENTS; FOLATE AND NEURAL TUBE DEFECTS (Docket No. 93N-0481/PSA2)
- (6). FOOD LABELING; HEALTH CLAIMS FOR ANTIOXIDANT VITAMINS AND CANCER (Docket No. 93N-480A/PSA2)
- (7). FOOD LABELING: HEALTH CLAIMS FOR DIETARY FIBER AND CORONARY VASCULAR DISEASE (Docket No. 93N-480C/PSA2)

- (8). FOOD LABELING; HEALTH CLAIMS FOR DIETARY FIBER AND CANCER (Docket No. 93N-0480F/PSA2)
- (9). FOOD LABELING; HEALTH CLAIMS FOR OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE (Docket No. 93N-0480O/PSA2)
- (10). FOOD LABELING; HEALTH CLAIMS FOR ZINC AND IMMUNE DEFICIENCY IN THE ELDERLY (Docket No. 93N-0480Z/PSA2)

These petitions were filed by FDA on February 7, 1994.

During the week of March 8, 2004, Dr. Susan Thompson unsuccessfully tried to contact Mr. Ronald Nesmith at the telephone number provided in the petition to ascertain whether the petitions that he submitted could be closed. Dr. Thompson also tried to find a telephone listing for Mr. Nesmith and/or for the National Council for Improved Health by contacting directory assistance in Chicago, Illinois. These attempts to contact Mr. Nesmith and the National Council for Improved Health were also unsuccessful as there was no telephone listing for either party.

In a certified letter dated March 19, 2004, Dr. Thompson asked Mr. Nesmith if he or the National Council for Improved Health were still interested in pursuing the issues set forth in their petitions in light of the fact that the issues raised in their petitions were now moot. The certified letter was returned to us on April 4, 2004, stamped "undeliverable as addressed, no forwarding order on file" (letter and envelope attached). We have searched the Internet and have not found any information that would enable us to contact either Mr. Nesmith or the National Council for Improved Health.

Because Mr. Ronald Nesmith and the National Council for Improved Health cannot be reached, FDA is closing the petitions listed above.

Susan Thompson, Ph.D.

Enclosures

DEPARTMENT OF LALTH AND HUMAN SERVICES



Food and Drug Administration College Park, MD 20740-38

MAR 1 9 2004

Mr. Ronald C. Nesmith Dilling and Dilling 150 North Wacker Drive Chicago, Illinois 60606

Re: Petitions for Stay of Action - Docket Numbers 93N-0478, 90N-135D, 91N-384D, 85N-061D, 93N-0481, 93N-480F, 93N-480C, 93N-4800, 93N-480A and 93N-480Z

Dear Mr. Nesmith:

This letter is in regards to ten citizen petitions submitted to the Food and Drug

Administration by you on behalf of the National Council for Improved Health concerning
labeling requirements for dietary supplements. These petitions were filed by FDA on
February 7, 1994.

The agency would appreciate an opportunity to discuss the matter of these petitions with you. However, we have been unable to contact you at the telephone number that you provided in your petition (i.e., (312) 236-8417). We would greatly appreciate you contacting us at your earliest convenience to discuss these petitions. Please contact me at (301) 436-1784 regarding this matter.

Sincerely yours,

Swan Thompson

Susan Thompson, Ph.D.

Chemist

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety

and Applied Nutrition